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| 10/645,970 | 08/22/2003 | Morteza Naghavi | D8562-16 | 8386 |
| 25397 | 7590 | 06/10/2008 | EXAMINER | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/645,970 | NAGHAVI ET AL. | |
| | Examiner | Art Unit | |
| | A. LAURITZEN | 3737 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) Responsive to communication(s) filed on 20 February 2008.

2a) This action is **FINAL**. 2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) Claim(s) 1-34 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) Claim(s) _____ is/are allowed.

6) Claim(s) 1-34 is/are rejected.

7) Claim(s) _____ is/are objected to.

8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All b) Some * c) None of:

1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

| | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ . | 6) <input type="checkbox"/> Other: _____ . |

This action is in response to communications filed 20 February 2008. The revised abstract has been acknowledged and entered. Claims 1 and 17 have been amended to include “defining an *anatomical* distribution of the areas of calcification within the located area,” but this feature is not supported by applicant’s specification; therefore, new grounds of rejection under the first paragraph of 35 U.S.C. 112 are presented herein.

Response to Arguments

Applicant's arguments have been fully considered but they are not persuasive and/or are moot in view of new grounds of rejection.

Applicant asserts that Hu et al., in determining an overall calcium score, teaches away from the claimed invention. Examiner disagrees. The claims as amended specify that a distribution of calcification is determined (including an anatomical distribution), and Strauss et al. is relied upon to establish that this technique is well known to artisans in the coronary calcification imaging arts. Unger et al. (US 7,105,828) is additionally cited to evidence that a calcium score represents “the total amount and distribution of calcium within the arteries” (col. 3, lines 63-67), which suggests that the total calcium score provides some indication for the total distribution of plaque and is a supplemental, quantitative measure of overall plaque distribution. Providing a total calcium score, as in the method of Hu et al., does not exclude measure of a distribution of calcified plaque. Additionally, applicant's remarks directed to performing statistical analyses and various mathematical methods are not relevant as these features are not actually claimed.

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. Claims 1-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Specifically, claims 1 and 17 have been amended to include “defining an *anatomical distribution* of the areas of calcification...” but this feature is not detailed in applicant’s specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-14, 17-28 and 31-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. (US 6,233,304) in view of Strauss et al. (US 2002/0115931).
Hu et al. disclose a method for detecting coronary artery calcification (CAC) by multi-slice helical reconstruction and/or electron beam computed tomography in a system with arrayed

detectors (col. 1, lines 13-15; 42-64). A distribution of calcification is acquired in the form of an attenuation transmission profile (col. 1, lines 19-21), with visualization of data giving rise to mapping sections of arteries or vessels of interest. System components are understood to include data storage and analysis components.

While Hu et al. do not specifically address determining the distribution of calcification, the total calcium score is a general quantitative indicator for both disease risk assessment and plaque distribution within the artery. Additionally, in the same field of endeavor, Strauss et al. teach localizing vascular lesions by characterizing and imaging the distribution of plaque within at the cellular level [0006-7]. The method includes determining the anatomical distribution of plaque, as it is disclosed that the azimuthal distribution is resolved [0007]. It would have been obvious to one of ordinary skill in the art at the time of invention to supplement the calcium score provided in the method of Hu et al. with a characterization of the anatomical distribution of plaque as taught by Strauss et al., in order to accurately resolve stable from vulnerable plaques [0006-7].

The method of Hu et al. includes calculation of x-ray attenuation coefficients in the form of CT numbers that are used in threshold comparison (col. 4, lines 15-36, in which a threshold of 130 HU is selected). The calcium score weighting algorithm for slice spacing correction would include determining changes in calcification density. Hu et al. further disclose plaque density assessment.

Regarding claim 11, Hu et al. do not explicitly disclose relating calcification densities to an outcome of a lesion; however, Strauss et al. teach that the presence of an atherosclerotic lesion reduces flow through the artery at the site of a lesion, and methods are known to measure this

difference [0003]. The image data are presented as pixel density scores and when displayed comprise a transmission profile or map (col. 4, lines 3-55). The progression of plaque is visible from pixel to pixel or from pixel densities across selected regions (col. 4, lines 3-5; 36-51).

3. Claims 12-14, 27 and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu et al. (US 6,233,304) in view of Strauss et al. (US 2002/0115931), as applied to claims 1 and 17 above, further in view of Kaufman et al. (US 2003/0095693).

Hu as appended by Strauss et al. includes all features of the invention as substantially claimed, including statistical calculation(s), with visualization of data resulting in a map of sections of vessels statistical distribution of calcification of each of a plurality of sections or regions (Hu et al., col. 4, in which a distribution of density scores of pixel values of regions of interest is obtained). Kaufman et al. teach calculation of an average and a range in determination of a peak value [0082]. It would have been obvious to one of ordinary skill in the art at the time of invention to quantify and statistically analyze the calcification data.

4. Claims 15 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable Hu, Strauss and Kaufman et al., as applied to claims 12-14, 27 and 28, further in view of O'Brien et al. (US 2004/0057955).

Hu and Strauss in view of Kaufman et al., as discussed above, includes all features of the invention as substantially claimed and while it can be inferred that a progression of plaque can be visualized in the plaque distribution image, it is not expressly disclosed that progression of plaque is determined; however, O'Brien further teaches a method for treating calcific aortic valve disease [0003-4], including monitoring the calcification and analysis of the progression of plaque. O'Brien further discloses performing statistical analyses on data obtained from scans

wherein the progression of the plaque can be observed to evaluate the relationship between progression of plaque and cardiovascular risk factors [0085-86]. It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Hu as appended by Strauss and Kaufman et al. in light of the teachings of O'Brien to include determination of progression of plaque to better characterize risk factors for cardiovascular disease.

5. Claim 16 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hu, Strauss, Kaufman and O'Brien et al., as applied to claim 15 and 29 above, further in view of Rather et al. (US 6,385,474).

Hu in view of Strauss, Kaufman and O'Brien, as discussed above, substantially disclose all features of the invention as claimed. While Hu et al. disclose categorizing regions according to calcification scores, neither Hu nor Kaufman explicitly disclose categorizing an area of abrupt change in elasticity as a high-risk region. Rather also discloses a method and apparatus for detection and characterization of medical pathologies, such as calcifications, and further teaches studying density and elasticity of the tissue [0013] in which microcalcifications and tissue elasticity are identified [0025]. Regions where there are abrupt changes are identified and each region is classified according to determined criterion [0087]. It would therefore have been obvious to one of ordinary skill in the art at the time of invention to modify that disclosed by Hu in view of Kaufman and O'Brien in light of the teachings of Rather to include ascertaining regions of abrupt changes which assists in the identification of microcalcifications and tissue elasticity which signal pathology such as cancer or calcified plaque.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Unger et al. (US 7,105,828) is cited to evidence that a calcium score represents "the total amount and distribution of calcium within the arteries" (col. 3, lines 63-67), which suggests that the total calcium score provides some indication for the total distribution of plaque and is a supplemental, quantitative measure of overall plaque distribution. Providing a total calcium score, as in the method of Hu et al., does not exclude measure of a distribution of calcified plaque.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to A. LAURITZEN whose telephone number is (571)272-4303. The examiner can normally be reached on Monday - Friday, 8:30am - 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian L. Casler can be reached on (571) 272-4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/A. L./
Examiner, Art Unit 3737

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